No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA INC. AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents leading biotechnology and pharmaceutical companies devoted to discovering and developing new and improved medicines.[1] Those efforts produce the cutting-edge treatments that save, prolong, and improve the quality of the lives of countless individuals around the world every day. Over the past decade, more than 350 new medicines have been approved by the Food and Drug Administration ("FDA"). In view of the risky research and development process, which has a significant failure rate of biopharmaceutical research and development, and the substantial requirements of the FDA to demonstrate safety and efficacy of new products, those results are not obtained cheaply. In 2016 alone, PhRMA members invested an estimated $65.5 billion in discovering and developing new medicines.

PhRMA seeks to advance public policies that foster innovation in new medicines, including by ensuring adequate patent protection to enable and incentivize its members' substantial investments in

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[1] Pursuant to Rule 37.6, PhRMA affirms that no counsel for a party authored this brief in whole or in part, and that no person other than amicus, its members, or its counsel made any monetary contributions intended to fund the preparation or submission of this brief. The parties were timely notified of PhRMA's intent to file this brief and consented to its filing. A complete list of PhRMA members is available at http://www.phrma.org/about/members (last visited Apr. 2, 2018). Members include Eisai Inc., Petitioner's U.S. marketing partner for Aloxi®, the product at issue in this case, and Teva US Specialty Medicines, a corporate affiliate of Respondents. Neither Eisai, Inc. nor Teva US Specialty Medicines contributed any money to fund the preparation of this brief.

research and development. To those ends, PhRMA seeks to remove barriers that may arise in the nation's systems, including the patent laws, for protecting the intellectual property of its members — including as *amicus curiae* before this Court.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case concerns the scope of the "on-sale" bar in patent law and whether and how the Leahy-Smith America Invents Act of 2011 (the "AIA") changed that scope. Petitioner argues in its brief that the amendments Congress introduced into the statutory definition of the on-sale bar in the AIA expressly limit the bar to sales that reveal to the public the details of the invention. Present Amicus Curiae joins those arguments and points out further that this Court's precedent suggests that the on-sale bar has always been so limited.

Innovators of all stripes—from solo inventors to pharmaceutical companies contemplating investments of billions of dollars to develop new medicines—require clarity in the law to make rational decisions about developing and commercializing their inventions. That clarity has been eroded by the Federal Circuit's decision in this case, which departs from both this Court's precedent and Congress's AIA amendments which restated the limitation of the on-sale bar to public sales. It also departs from the Government's implementation of the restated limitation. The Federal Circuit's departure from this Court, Congress, and the Government has created considerable confusion and doubt in the patent community that will persist until this Court corrects the Federal Circuit's decision. Our nation's innovation economy will

continue to suffer damage in the interim. Present Amicus Curiae joins Petitioner in urging this Court to grant certiorari now to minimize that damage.

ARGUMENT

I. Review is warranted because the Federal Circuit's decision calls into question countless issued or pending patents.

Over 1 million U.S. patents have issued, and about 3 million U.S. patent applications have been filed, since the revised on-sale bar provisions of the Leahy-Smith America Invents Act of 2011 (the "AIA") took effect on March 16, 2013.[2] Many of these patents, and innumerable more to come, are now clouded with uncertainty about the scope of the on-sale bar, for the reasons laid out in the petition. The inventions described and claimed in these patents are the work of innovators from all walks of life, from solo inventors to proprietors of small companies to scientists in the R&D divisions of large companies. They unexpectedly face a new doubt, however: whether pre-filing sales of those inventions bar their patents.

The doubt is unexpected because the AIA revisions to the on-sale bar were intended by Congress, and were implemented by the Government, to limit the on-sale bar unambiguously to sales that revealed to the public the details of the invention, as explained in the Government's *amicus curiae* brief on the merits in support of Petitioner before the Federal Circuit.

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[2] Figures compiled from USPTO Performance and Accountability Report for Fiscal Year 2017, Tables 1 (p. 168) and 6 (p. 171). URL: https://www.uspto.gov/sites/default/files/documents/USPTOFY17PAR.pdf

Gov't C.A. Br. 7–8. Sales from which the nature of the claimed invention could not be determined would not trigger the on-sale bar. *Id.*

To that end, The Patent Office promulgated examination guidelines excluding such non-public sales from the on-sale bar. *Id.* at 5 (citing *Examination Guidelines for Implementing the First Inventor To File Provisions of the Leahy-Smith America Invents Act*, 78 Fed. Reg. 11,059, 11,062 (Feb. 14, 2013). Before this guidance was issued, the Patent Office followed Federal Circuit precedent that did not exclude non-public sales from the on-sale bar. The Federal Circuit's failure to exclude non-public sales from the on-sale bar was erroneous for reasons discussed in the next section of this brief.

Pharmaceutical companies and other patent applicants have been making business decisions about how to structure commercial agreements, and when to file for patents, in reliance on clear and unambiguous statements from Congress, the courts, and the Government defining what activities would—and would not—imperil their ability to patent their inventions. The Federal Circuit's abrupt and ill-considered repudiation of Congress and the Government introduces significant uncertainty into the patent system, shifting the firm ground on which stakeholders had made decisions about how to protect their valuable intellectual property.

This upheaval has thrown into doubt the validity of countless patents and patent applications subject to the AIA definition of prior art. A number of those patents may cover potentially important new medicines or other technologies. Consider a pharmaceutical company that relied on the patent statute to pursue a

research and development program for a patented drug candidate despite earlier activities that might be characterized as "sales" but did not make the claimed invention publicly available. Loss of the patent might prompt the company to abandon its research and development efforts. Or consider a company that fully discloses an invention in a patent application following an earlier non-public sale. That company now would find itself considerably worse off than if it never had filed a patent application at all; it now might get nothing in exchange for a complete disclosure of a claimed invention in the patent.

The scope of such perverse results has not yet been ascertained, but it is likely significant. It is ultimately the public that suffers the loss of important new inventions when companies abandon their development or choose trade secrecy over full disclosure in a patent. Review now can correct the Federal Circuit's error, provide the incentives and limitations that Congress carefully crafted in the AIA, and restore stability to the examination of patent applications under the AIA. If the Federal Circuit's opinion is allowed to stand, the validity questions lingering over pending and issued patents will continue to be litigated for the foreseeable future.

The issue presented by this case is of exceptional importance to companies engaged in pharmaceutical research, because they depend on patents to protect the large investments they make in R&D and must make decisions about investments in research programs years before they can market a product. The success or failure of a pharmaceutical product can rise or fall on the fate of just one or a handful of patents, so uncertainty in a patent's valuation or validity can

significantly impair a pharmaceutical company's ability to generate revenue to support the research and development of new products. And uncertainty in the definition of what kinds of commercial agreements run afoul of the on-sale bar imperils manufacturing and distribution relationships that small companies, in particular, rely on to bring products to market. This is important in an area where there are large and small companies that can be working collaboratively, as well as academic research centers.

Companies have made significant investments, engaged in costly research, filed patent applications, and structured their business dealings, in reliance on their understanding of what activities would and would not give rise to prior art that could be used against their own patents. The Federal Circuit decision upends those expectations and puts innumerable patents at risk. Companies need clear and consistent standards to structure their operations if they are to spend years and hundreds of millions of dollars in R&D developing new treatments for patients that rely on patent protection.

II. Review is warranted because the Federal Circuit misread this Court's precedent and ignored the express enactment by Congress of the AIA.

This Court's on-sale bar precedent reaches only those sales that reveal to the public the details of the invention, whereas the Federal Circuit has extended the bar to those that do not.

This case provides an ideal opportunity for this Court to rule on the scope of the on-sale bar. In present Amicus Curiae's view, the proper scope is the one

this Court's precedents point to: that the bar is limited to sales that reveal the details of the invention to the public, and not to the rule the Federal Circuit has adopted, which extends the bar to sales from which the public cannot glean the invention. Review is appropriate to correct the Federal Circuit's rule.

Petitioner's brief explains in detail how the AIA added language to the on-sale bar provision to state expressly that the bar was limited to public sales. But in fact, this Court has never held the on-sale bar to extend to non-public sales. As such, the on-sale bar was amended not to restrict it to public sales, but rather to overrule legislatively the Federal Circuit's own extension of the on-sale bar to non-public sales. Gov't C.A. Br. 7–8 ("Congress in the AIA amended the on-sale bar to correct that error and restore the historical meaning of the phrase 'on sale.'").

The restriction of the on-sale bar to public sales has been a part of U.S. patent law at least since 1829, when this Court recognized that an inventor's "voluntary act . . . in the public sale and use is an abandonment of" the patent right. *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 24 (1829). The emphasis was on abrogating the patent rights of an inventor who failed to seek timely patent protection after allowing the invention "to be publicly sold for use." *Id.* at 23–24. The contours of the on-sale bar changed little over the years, even with the most sweeping of revisions to the patent law in 1952. Gov't C.A. Br. 7 ("In the ensuing 180 years [following the enactment of the Patent Act of 1836], during which Congress repeatedly reenacted the on-sale bar without materially changing its text, the Supreme Court has reiterated that the on-sale bar encompasses only public sales."). This Court's

most recent treatment of the on-sale bar re-emphasized its public nature. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998) (recognizing the "reluctance to allow an inventor to remove existing knowledge from public use" as the basis of the on-sale bar).

The Federal Circuit nonetheless expanded the on-sale bar to non-public sales based on this Court's citation in *Pfaff* to the Second Circuit case, *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946). *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc. et al*, No. 16-1284 (Fed. Cir. Jan. 16, 2018), sl. op. at 3–4 n.1 (O'Malley, Circuit J., concurring in the denial of panel rehearing) ("the Supreme Court seems to have endorsed the general principles articulated in *Metallizing*"); *see also* Gov't C.A. Br. 7–8 (tracing Federal Circuit's creation of the non-public sales rule). The Second Circuit in *Metallizing* had held that a patent to a manufacturing process was invalid over prior public sales of articles made secretly with the process. *Metallizing*, 153 F.2d at 517–18.

The Federal Circuit mistakenly assumed, however, that this Court endorsed a broader reading of the on-sale bar in *Pfaff*. This Court in *Pfaff* addressed only whether a commercial sale of an invention "ready for patenting," but not yet reduced to practice, barred the patent. *Pfaff*, 525 U.S. 66. Thus this Court's favorable citation to *Metallizing* in *Pfaff* (525 U.S. at 68) was dicta.[3] And this Court's view that the on-sale bar applies only to sales that put the public in possession of

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[3] For a summary of the facts in *Metallizing* and the subsequent development of the eponymous doctrine, see Karshtedt, D., *Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of Metallizing Engineering*, 57 Vill. L. Rev. 261 (2012).

the invention is clear from the repeated references in *Pfaff* to the "public." *E.g.*, *Pfaff*, 525 U.S. at 64 (Congressional "reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar").

Moreover, the Second Circuit in *Metallizing* recognized that its rule was contrary to that of other courts of appeal, including the Federal Circuit's own predecessor, the Court of Customs and Patent Appeals. In *Stresau v. Ipsen*, 77 F.2d 937 (CCPA 1935), the Federal Circuit's predecessor court held that a "process claim might be valid when the inventor had kept the process secret but had sold the product." *Metallizing*, 153 F.2d at 519 (citing *Stresau*).[4]

It is clear, then, that the Federal Circuit's extension of the on-sale bar to sales that do not reveal the invention to the public is an outgrowth of dicta that runs counter to this Court's binding precedent. Given the length of time this aspect of the on-sale bar has evaded review and the Federal Circuit's determination to maintain its erroneous doctrine despite legislative overrule by Congress with the AIA, review now is timely.

CONCLUSION

For the foregoing reasons and those set forth in the petition for a writ of *certiorari*, the Court should grant the petition.

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[4] The Federal Circuit adopted as binding precedent the opinions of its predecessor courts. *South Corp. v. United States*, 690 F.2d 1368 (Fed. Cir. 1982).

Respectfully submitted,

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